State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

* The agency identified below in box 1 provides notice of proposed rule change pursuant to Utah Code Section 63G-3-301.
* Please address questions regarding information on this notice to the agency.
* The full text of all rule filings is published in the Utah State Bulletin unless excluded because of space constraints.
* The full text of all rule filings may also be inspected at the Division of Administrative Rules.

DAR file no:		Date filed:	
State Admin Rule Filing Id:		Time filed:	

		Agency No.		Rule No.		Section No.
Utah Admin. Code Ref (R no.):	**R**	156	-	17b	-	
Changed to Admin. Code Ref. (R no.):	**R**		-		-	

1. Agency: Commerce/Division of Occupational and Professional Licensing

Room no.:	
Building:	Heber M. Wells Building
Street address 1:	160 East 300 South
Street address 2:	
City, state, zip:	Salt Lake City UT 84111-2316
Mailing address 1:	PO Box 146741
Mailing address 2:	
City, state, zip:	Salt Lake City UT 84114-6741

Contact person(s):

Name:	Phone:	Fax:	E-mail:
Rich Oborn	801-530-6767	801-530-6511	roborn@utah.gov

(Interested persons may inspect this filing at the above address or at the Division of Administrative Rules during business hours)

2. Title of rule or section (catchline)**:**

Pharmacy Practice Act Rule

3. Type of notice:

New ___; Amendment xx; Repeal ___; Repeal and Reenact ___

4. Purpose of the rule or reason for the change:

S.B. 161 was passed during the 2012 Legislative Session. This bill exempts an oncologist or medical personnel acting under the direction of an oncologist from being licensed under the Pharmacy Practice Act to dispense a cancer drug regimen to a patient who is undergoing chemotherapy in an outpatient clinic setting if labeling, record keeping, patient counseling, storage, purchasing and distribution, operating, treatment, and quality of care requirements established by administrative rule adopted by the Division in consultation with the Board are followed. This amendment establishes these requirements. Other rule amendments are made at the request of the Pharmacy Board and due to the passing of S.B. 194 during the 2013 Legislative Session.

5. This change is a response to comments from the Administrative Rules Review Committee.

No XXX; Yes ___

6. Summary of the rule or change:

	The following rule amendments are made throughout R156-17b: capitalization, updating of references, renumbering of paragraphs, and minor grammatical changes. Section 102: Updated the United States Pharmacoepia-National Formulary (USP-NF) to the most current May 1, 2013 edition. Section R156-17b-303a: Subsection (3)(e)increases the amount of time permitted for a pharmacy technician-in-training to complete the pharmacy technician program and obtain licensure from one year to two years. It also clarifies that a technician-in-training who is not licensed within two years is only allowed to work as supportive personnel in a pharmacy and must repeat a pharmacy technician training program in its entirety for licensure. The current rule requires licensure within a year, which was not a reasonable time frame for countless students and special accommodation requests occupied an inordinate amount of Pharmacy Board and licensing staff time. The current rule is confusing and difficult to interpret. This rule amendment is very clear and student-friendly. Section R156-17b-303b: This section equalizes the internship requirements for graduates of all U.S. and foreign pharmacy schools and mirrors the national standards set by the Accreditation Council for Pharmacy Education (ACPE). Over time, pharmacy internship standards for U.S. graduates became more rigorous, while foreign graduates/licensees were exempt from the rigor required by U.S. schools. In addition, Utah graduates were at a disadvantage when compared to pharmacists licensed by endorsement from other states due to a much higher internship hour requirement in Utah when compared to other states. Section R156-17b-310: In accordance with Section 58-17b-309.5, requirements for dispensing cancer drug treatment regimen drugs are established, mirroring the requirements set forth in rule for dispensing cosmetic and injectable weight loss drugs. Subsection (11) sets forth standards for reporting to the Utah Controlled Substance Database for practitioners exempt from licensure as a pharmacist, consistent with the Utah Controlled Substance Database Act and Rule. Section R156-17b-605: Subsection (1)(k) renumbers Subsection (7). Subsection (2)(d) clarifies requirements for both opening and closing pharmacy inventories when two pharmacies are combined. Section R156-17b-614a: This section clarifies and implements standards for procurement of compounding ingredients. It also eliminates the requirement for filing an investigational new drug application (IND) when a pharmacist engages in compounding using drugs that are not part of an FDA-approved drug list, in accordance with national guidelines in USP-NF Chapters 795 and 797. Section R156-17b-614e: The title of this section is changed to reflect the more current intent of the rule.
7.	**Aggregate anticipated cost or savings to:**
	A) State budget:
	Affected: No ___; Yes XX
	The Division may incur increased costs related to inspecting dispensing practitioners' offices, filing on or citing providers and holding hearings. Controlled Substance Database (CSD) staff may spend more time teaching dispensing practitioners how to submit reports to and utilize the CSD. Allowing pharmacy technician students two years to complete training and licensing may decrease Division workload. However, the Division is unable to quantify the impact of these changes.. The Division is also required to purchase two copies of the current edition of the USP-NF books at an annual renewal cost of approximately $1,800.
	B) Local government:
	Affected: No XXX; Yes ___
	The proposed amendments only apply to licensed pharmacists, pharmacies, pharmacy technicians and pharmacy interns and applicants for licensure in those classifications. As a result, the proposed amendments do not apply to local governments.
	C) Small businesses ("small business" means a business employing fewer than 50 persons)**:**
	Affected: No ___; Yes XXX
	The small businesses most likely to be affected are provider offices and small pharmacies. Provider offices may see an increase in patients due to the convenience of provider dispensing, while pharmacies may see a corresponding decrease in business. Pharmacies may also be positively impacted by technicians being allowed two years to complete a pharmacy technician program and licensing. However, the Division is unable to quantify the impact on small businesses. Also, it is unknown to the Division how many providers will choose to dispense medications.
	D) Persons other than small businesses, businesses, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an agency)**:**
	Affected: No ___; Yes XXX

	Patients will be affected by provider dispensing. It is anticipated that the applicable amendments will result in more convenience and satisfaction for patients because they will not have to travel to the pharmacy and wait in line to have their prescriptions filled, particularly during treatment for cancer.
8.	**Compliance costs for affected persons:**
	Dispensing practitioners may have to remodel their offices, hire additional staff and improve office security. However, the Division is unable to quantify these potential costs to providers due to a wide range of circumstances.
9.	**A) Comments by the department head on the fiscal impact the rule may have on businesses:**
	These amendments are proposed primarily to make changes that are required under S.B. 161 (2012 Legislative Session). No costs to businesses are anticipated beyond those considered by the Legislature in determining to pass the bill. The remaining amendments make clarifications and nonsubstantive corrections, with no attendant costs to businesses.
	B) Name and title of department head commenting on the fiscal impacts:
	Francine A. Giani, Executive Director
10.	**This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.** **State code or constitution citations (required)** (e.g., Section 63G-3-402; Subsection 63G-3-601(3); Article IV) **:**

Section 58-17b-101	Subsection 58-17b-601(1)
Section 58-37-1	Subsection 58-1-106(1)(a)
Subsection 58-1-202(1)(a)	

11. **This rule adds, updates, or removes the following title of materials incorporated by references** (a copy of materials incorporated by reference must be submitted to the Division of Administrative Rules; *if none, leave blank*)**:**

	First Incorporation	**Second Incorporation**
Official Title of Materials Incorporated (from title page)	USP 36-NF 31	Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree Guidelines Version 2.0
Publisher	United States Pharmacopeia	Accreditation Council for Pharmacy Education (ACPE)
Date Issued	May 1, 2013	February 14, 2011
Issue, or version		
ISBN Number (optional)		
ISSN Number (optional)		
Cost of Incorporated Reference	$900.00	
Action: Adds, updates, or removes	Updates	Adds

(If this rule incorporates more than two items by reference, please attach additional pages)

12. **The public may submit written or oral comments to the agency identified in box 1.** (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy)**:**	07/31/2013

B) A public hearing (optional) will be held:

On (mm/dd/yyyy)**:**	**At** (hh:mm AM/PM)**:**	**At** (place)**:**
07/30/2013	8:30 AM	160 East 300 South, Conference Room 474, Salt Lake City, Utah

13. **This rule change may become effective on** (mm/dd/yyyy)**:** 08/07/2013

	NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 12(A) above, the agency must submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.	
14.	**Indexing information -- keywords** (maximum of four, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid"); may not include the name of the agency**:**	
	pharmacists	licensing
	pharmacies	
15.	**Attach an RTF document containing the text of this rule change** (filename)**:**	R156-17b.pro

To the agency: Information requested on this form is required by Sections 63G-3-301, 302, 303, and 402. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency head or designee, and title:	Mark B. Steinagel, Director	**Date** (mm/dd/yyyy)**:**	06/10/2013

R156. Commerce, Occupational and Professional Licensing.
R156-17b. Pharmacy Practice Act Rule.
R156-17b-101. Title.

This rule is known as the "Pharmacy Practice Act Rule".

R156-17b-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 17b, as used in Title 58, Chapters 1 and 17b or this rule:

(1) "ACPE" means the American Council on Pharmaceutical Education or Accreditation Council for Pharmacy Education.

(2) "Analytical laboratory":

(a) means a facility in possession of prescription drugs for the purpose of analysis; and

(b) does not include a laboratory possessing prescription drugs used as standards and controls in performing drug monitoring or drug screening analysis if the prescription drugs are pre-diluted in a human or animal body fluid, human or animal body fluid components, organic solvents, or inorganic buffers at a concentration not exceeding one milligram per milliliter when labeled or otherwise designated as being for in-vitro diagnostic use.

(3) "Authorized distributor of record" means a pharmaceutical wholesaler with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drugs. An ongoing relationship is deemed to exist between such pharmaceutical wholesaler and a manufacturer, as defined in Section 1504 of the Internal Revenue Code, when the pharmaceutical wholesaler has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship, and the pharmaceutical wholesaler is listed on the manufacturer's current list of authorized distributors of record.

(4) "Authorized personnel" means any person who is a part of the pharmacy staff who participates in the operational processes of the pharmacy and contributes to the natural flow of pharmaceutical care.

(5) "Centralized Prescription Filling" means the filling by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order.

(6) "Centralized Prescription Processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

(7) "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and

performs intracompany sales or transfers of the prescription drugs to a group of chain pharmacies that have the same common ownership and control.

(8) "Co-licensed partner or product" means an instance where two or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with FDA's implementation of the Prescription Drug Marketing Act.

(9) "Cooperative pharmacy warehouse" means a physical location for drugs that acts as a central warehouse and is owned, operated or affiliated with a group purchasing organization (GPO) or pharmacy buying cooperative and distributes those drugs exclusively to its members.

(10) "Counterfeit prescription drug" has the meaning given that term in 21 USC 321(g)(2), including any amendments thereto.

(11) "Counterfeiting" means engaging in activities that create a counterfeit prescription drug.

(12) "Dispense", as defined in Subsection 58-17b-102([~~23~~]22), does not include transferring medications for a patient from a legally dispensed prescription for that particular patient into a daily or weekly drug container to facilitate the patient taking the correct medication.

(13) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under Federal law to bear the label, "Caution: Federal or State law requires dispensing by or on the order of a physician."

(14) "Drop shipment" means the sale of a prescription drug to a pharmaceutical wholesaler by the manufacturer of the drug; by the manufacturer's co-licensed product partner, third party logistics provider, or exclusive distributor; or by an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities; whereby:

(a) the pharmaceutical wholesale distributor takes title to but not physical possession of such prescription drug;

(b) the pharmaceutical wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense to administer such drug; and

(c) the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer such drug receives delivery of the prescription drug directly from the manufacturer; from the co-licensed product partner, third party logistics provider, or exclusive distributor; or from an authorized distributor of record that purchases the product directly from the manufacturer or from one of these entities.

(15) "Drug therapy management" means the review of a drug therapy regimen of a patient by one or more pharmacists for the purpose of evaluating and rendering advice to one or more practitioners regarding adjustment of the regimen.

(16) "Drugs", as used in this rule, means drugs or devices.

(17) "Durable medical equipment" or "DME" means equipment that:

(a) can withstand repeated use;

(b) is primarily and customarily used to serve a medical purpose;

(c) generally is not useful to a person in the absence of an illness or injury;

(d) is suitable for use in a health care facility or in the home; and

(e) may include devices and medical supplies.

(18) "ExCPT", as used in this rule, means the Exam for the Certification of Pharmacy Technicians.

(19) "FDA" means the United States Food and Drug Administration and any successor agency.

(20) "High-risk, medium-risk, and low-risk drugs" refers to the risk to a patient's health from compounding sterile preparations, as referred to in USP-NF Chapter 797, for details of determining risk level.

(21) "Hospice facility pharmacy" means a pharmacy that supplies drugs to patients in a licensed healthcare facility for terminal patients.

(22) "Hospital clinic pharmacy" means a pharmacy that is located in an outpatient treatment area where a pharmacist or pharmacy intern is compounding, admixing, or dispensing prescription drugs, and where:

(a) prescription drugs or devices are under the control of the pharmacist, or the facility for administration to patients of that facility;

(b) prescription drugs or devices are dispensed by the pharmacist or pharmacy intern; or

(c) prescription drugs are administered in accordance with the order of a practitioner by an employee or agent of the facility.

(23) "Legend drug" or "prescription drug" means any drug or device that has been determined to be unsafe for self-medication or any drug or device that bears or is required to bear the legend:

(a) "Caution: federal law prohibits dispensing without prescription";

(b) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(c) "Rx only".

(24) "Maintenance medications" means medications the patient takes on an ongoing basis.

(25) "Manufacturer's exclusive distributor" means an entity that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the drug's sale or disposition. Such manufacturer's exclusive distributor [~~must~~]shall be licensed as a pharmaceutical wholesaler under this chapter and be an "authorized distributor of record" to be considered part of the "normal distribution channel".

(26) "Medical supplies" means items for medical use that are suitable for use in a health care facility or in the home and that are disposable or semi-disposable and are non-reusable.

(27) "MPJE" means the Multistate Jurisprudence Examination.

(28) "NABP" means the National Association of Boards of Pharmacy.

(29) "NAPLEX" means North American Pharmacy Licensing Examination.

(30) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly, by drop shipment as defined in Subsection ([~~12~~]14), or via intracompany transfer from a manufacturer; or from the manufacturer's co-licensed partner, third-party logistics provider, or the exclusive distributor to:

(a) a pharmacy or other designated persons authorized under this chapter to dispense or administer prescription drugs to a patient;

(b) a chain pharmacy warehouse that performs intracompany sales or transfers of such drugs to a group of pharmacies under common ownership and control;

(c) a cooperative pharmacy warehouse to a pharmacy that is a member of the pharmacy buying cooperative or GPO to a patient;

(d) an authorized distributor of record, and then to either a pharmacy or other designated persons authorized under this chapter to dispense or administer such drug for use by a patient;

(e) an authorized distributor of record, and then to a chain pharmacy warehouse that performs intracompany sales or transfers of such drugs to a group of pharmacies under common ownership and control; or

(f) an authorized distributor of record to another authorized distributor of record to a licensed pharmaceutical facility or a licensed healthcare practitioner authorized under

this chapter to dispense or administer such drug for use by a patient.

(31) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

(32) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.

(33) "PIC", as used in this rule, means the pharmacist-in-charge.

(34) "Prescription files" means all hard-copy and electronic prescriptions that includes pharmacist notes or technician notes, clarifications or information written or attached that is pertinent to the prescription.

(35) "PTCB" means the Pharmacy Technician Certification Board.

(36) "Qualified continuing education", as used in this rule, means continuing education that meets the standards set forth in Section R156-17b-309.

(37) "Refill" means to fill again.

(38) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding that completed by the pharmacist responsible for dispensing the product to a patient.

(39) "Reverse distributor" means a person or company that retrieves unusable or outdated drugs from a pharmacy or pharmacist for the purpose of removing those drugs from stock and destroying them.

(40) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic technique.

(41) "Supervisor" means a licensed pharmacist in good standing with the Division.

(42) "Third party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but does not take title to the prescription drug or have any authoritative control over the prescription drug's sale. Such third party logistics provider [~~must~~]shall be licensed as a pharmaceutical wholesaler under this chapter and be an "authorized distributor of record" to be considered part of the "normal distribution channel".

(43) "Unauthorized personnel" means any person who is not participating in the operational processes of the pharmacy who in some way would interrupt the natural flow of pharmaceutical care.

(44) "Unit dose" means the ordered amount of a drug in a dosage form prepared for a one-time administration to an

individual and indicates the name, strength, lot number and expiration date for the drug.

(45) "Unprofessional conduct", as defined in Title 58, Chapters 1 and 17b, is further defined, in accordance with Subsection 58-1-203(1)(e), in Section R156-17b-502.

(46) "USP-NF" means the United States Pharmacopeia-National Formulary (USP [~~35~~]36-NF [~~30~~]31), 201[~~2~~]3 edition, which is official from May 1, [~~2012~~]2013 through Supplement 2, dated December 1, 2012, which is hereby adopted and incorporated by reference.

(47) "Wholesaler" means a wholesale distributor who supplies or distributes drugs or medical devices that are restricted by federal law to sales based on the order of a physician to a person other than the consumer or patient.

(48) "Wholesale distribution" means the distribution of drugs to persons other than consumers or patients, but does not include:

(a) intracompany sales or transfers;

(b) the sale, purchase, distribution, trade, or other transfer of a prescription drug for emergency medical reasons, as defined under 21 CFR 203.3(m), including any amendments thereto;

(c) the sale, purchase, or trade of a drug pursuant to a prescription;

(d) the distribution of drug samples;

(e) the return or transfer of prescription drugs to the original manufacturer, original wholesale distributor, reverse distributor, or a third party returns processor;

(f) the sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record during a time period for which there is documentation from the manufacturer that the manufacturer is able to supply a prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(g) the sale, purchase or exchange of blood or blood components for transfusions;

(h) the sale, transfer, merger or consolidation of all or part of the business of a pharmacy;

(i) delivery of a prescription drug by a common carrier; or

(j) other transactions excluded from the definition of "wholesale distribution" under 21 CFR 203.3 (cc), including any amendments thereto.

R156-17b-303a. Qualifications for Licensure - Education

Requirements.

(1) In accordance with Subsections 58-17b-303(2) and 58-17b-304(7)([~~c~~]b), the credentialing agency recognized to provide certification and evaluate equivalency of a foreign educated pharmacy graduate is the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy Foundation.

(2) In accordance with Subsection 58-17b-304([~~6~~]7), an applicant for a pharmacy intern license shall demonstrate that he meets one of the following education criteria:

(a) current admission in a College of Pharmacy accredited by the ACPE by written verification from the Dean of the College;

(b) a graduate degree from a school or college of pharmacy which is accredited by the ACPE; or

(c) a graduate degree from a foreign pharmacy school as established by a certificate of equivalency from an approved credentialing agency defined in Subsection (1).

(3) In accordance with Subsection 58-17b-305(1)(f), a pharmacy technician [~~must~~]shall complete an approved program of education and training that meets the following standards:

(a) The didactic training program [~~must~~]shall be approved by the Division in collaboration with the Board and [~~must~~]shall address, at a minimum, the following topics:

(i) legal aspects of pharmacy practice including federal and state laws and rules governing practice;

(ii) hygiene and aseptic techniques;

(iii) terminology, abbreviations and symbols;

(iv) pharmaceutical calculations;

(v) identification of drugs by trade and generic names, and therapeutic classifications;

(vi) filling of orders and prescriptions including packaging and labeling;

(vii) ordering, restocking, and maintaining drug inventory;

(viii) computer applications in the pharmacy; and

(ix) non-prescription products including cough and cold, nutritional, analgesics, allergy, diabetic testing supplies, first aid, ophthalmic, family planning, foot, feminine hygiene, gastrointestinal preparations, and pharmacy care over-the-counter drugs, except those over-the-counter drugs that are prescribed by a practitioner.

(b) This training program's curriculum and a copy of the final examination shall be submitted to the Division for approval by the Board prior to starting any training session with a pharmacy technician in training. The final examination [~~must~~]shall include questions covering each of the topics listed

in Subsection (3)(a) above.

(c) Approval [~~must~~]shall be granted by the Division in collaboration with the Board before a student may start a program of study. An individual who completes a non-approved program is not eligible for licensure.

(d) The training program shall include:

(i) at least 180 but not more than 360 hours of directly supervised practical training as determined appropriate by the supervisor; and

(ii) written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technicians in training that address:

(A) the specific manner in which supervision will be completed; and

(B) an evaluative procedure to verify the accuracy and completeness of all acts, tasks and functions performed by the pharmacy technician in training.

(e)(i) An individual [~~must~~]shall complete an approved training program and successfully pass the required examinations as listed in Subsection R156-17b-[~~302(3)~~]303(b)(4) within [~~one~~]two years from the date of the first day of the training program, unless otherwise approved by the Division in collaboration with the Board.

(ii) An individual who has completed an approved program, but did not seek licensure within the [~~one~~]two-year time frame [~~shall~~]:

(A) is no longer eligible for employment as a technician-in-training and shall work in the pharmacy only as supportive personnel; and[~~complete a minimum of an additional 180 but not more than 360 hours of directly supervised refresher practice, as determined by the supervisor, in a pharmacy approved by the Board if it has been more than six months since having practiced in a pharmacy setting and less than two years since the initial start date of the program; or~~]

(B) shall repeat an approved pharmacy technician training program in its entirety if the individual pursues licensure as a pharmacy technician[~~it has been greater than two years since the initial start date of the program~~].[

~~(ii) An individual who has been licensed as a pharmacy technician but allowed that license to expire for more than six months but less than two years and wishes to renew that license must complete a minimum of 180 but not more than 360 hours of directly supervised refresher practice, as determined appropriate by the supervisor, in a pharmacy approved by the Board.~~

~~(iii) An individual who has completed an approved program, but is awaiting the results of the required examinations may~~

~~practice as a technician-in-training under the direct supervision of the pharmacist for a period not to exceed three months. If the individual fails the examinations, that individual can no longer work as at technician-in-training while waiting to retake the examinations. The individual shall work in the pharmacy only as supportive personnel.~~]

(4) An applicant for licensure as a pharmacy technician is deemed to have met the qualifications for licensure in Subsection 58-17b-305(1)(f) and 58-17b-305(1)(g) if the applicant:

(a) is currently licensed and in good standing in another state and has not had any adverse action taken on that license;

(b) has engaged in the practice as a pharmacy technician for a minimum of 1,000 hours in that state within the past two years or equivalent experience as approved by the Division in collaboration with the Board;

(c) has passed and maintained current PTCB or ExCPT certification; and

(d) has passed the Utah Pharmacy Technician Law and Rule Examination.

R156-17b-303b. Licensure - Pharmacist - Pharmacy Internship Standards.

(1) In accordance with Subsection 58-17b-303(1)(g), the standards for the pharmacy internship required for licensure as a pharmacist for graduates of all U.S. and foreign pharmacy schools, include the following:

(a) At least 1740 hours of practice supervised by a pharmacy preceptor shall be obtained in Utah or another state or territory of the United States, or a combination of both according to the Accreditation Council for Pharmacy Education (ACPE), Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree Guidelines Version 2.0 Effective February 14, 2001, which is hereby incorporated by reference[~~1500 hours of practice supervised by a pharmacy preceptor shall be obtained in Utah or another state or territory of the United States, or a combination of both~~].

(i) Introductory pharmacy practice experiences (IPPE) shall account for not less than 300 hours over the first three professional years.[~~Internship hours completed in Utah shall include at least 360 hours but not more than 900 hours in a college coordinated practical experience program as an integral part of the curriculum which shall include a minimum of 120 hours in each of the following practices:~~

~~(A) community pharmacy;~~

~~(B) institutional pharmacy; and~~

~~(C) any clinical setting.~~]

(ii) A minimum of 150 hours shall be balanced between community pharmacy and institutional health system settings.

(iii) Advanced pharmacy practice experiences (APPE) shall include at least 1440 hours (i.e., 36 weeks) during the last academic year and after all IPPE requirements are completed.

(iv) Required experiences shall:

(A) include primary, acute, chronic, and preventive care among patients of all ages; and

(B) develop pharmacist-delivered patient care competencies in the community pharmacy, hospital or health-system pharmacy, ambulatory care, inpatient/acute care, and general medicine settings.

([~~ii~~]v) Internship hours completed in another state or territory of the United States shall be accepted based on the approval of the hours by the pharmacy board in the jurisdiction where the hours were obtained.

(b) Evidence of completed internship hours shall be documented to the Division by the pharmacy intern at the time application is made for a Utah pharmacist license.

(c) Pharmacy interns participating in internships may be credited no more than 50 hours per week of internship experience.

(d) No credit will be awarded for didactic experience.

(2) If a pharmacy intern is suspended or dismissed from an approved College of Pharmacy, the intern [~~must~~]shall notify the Division within 15 days of the suspension or dismissal.

(3) If a pharmacy intern ceases to meet all requirements for intern licensure, the pharmacy intern shall surrender the pharmacy intern license to the Division within 60 days unless an extension is requested and granted by the Division in collaboration with the Board.

R156-17b-303c. Qualifications for Licensure - Examinations.

(1) In accordance with Subsection 58-17b-303(1)(h), the examinations that [~~must~~]shall be successfully passed by an applicant for licensure as a pharmacist are:

(a) the NAPLEX with a passing score as established by NABP; and

(b) the Multistate Pharmacy Jurisprudence Examination(MPJE) with a minimum passing score as established by NABP.

(2) An individual who has failed either examination twice shall meet with the Board to request an additional authorization to test. The Division, in collaboration with the Board, may require additional training as a condition for approval of an authorization to retest.

(3) In accordance with Subsection 58-17b-303(3)(j), an applicant applying by endorsement is required to pass the MPJE.

(4) In accordance with Subsection 58-17b-305(1)(g), the examinations which [~~must~~]shall be passed by an applicant applying for licensure as a pharmacy technician are:

(a) the Utah Pharmacy Technician Law and Rule Examination, taken as part of the application for licensure, with a minimum passing score of 88 percent; and

(b) the PTCB or ExCPT with a passing score as established by the certifying body. The certificate [~~must~~]shall exhibit a valid date and that the certification is active.

(5) A graduate of a foreign pharmacy school shall obtain a passing score on the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination.

R156-17b-310. Exemption from Licensure - Dispensing of Cosmetic, [~~or~~] Injectable Weight Loss, or Cancer Drug Treatment Regimen Drugs.

(1) A cosmetic drug that can be dispensed by a prescribing practitioner or optometrist in accordance with Subsection 58-17b-309 is limited to Latisse.

(2) An injectable weight loss drug that can be dispensed by a prescribing practitioner in accordance with Subsection 58-17b-309 is limited to human chorionic gonadotropin.

(3) A cancer drug treatment regimen that can be dispensed by a prescribing practitioner or an individual employed by the prescribing practitioner in accordance with Subsection 58-17b-309.5(1) and (2) means a prescription drug used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient.

(a) A prescribing practitioner who chooses to dispense prescription medications shall disclose to the patient that the cancer drug treatment regimen may be obtained from a pharmacy unaffiliated with the prescribing practitioner and offer to the patient the opportunity to consult with a pharmacist if the patient desires patient counseling.

(b) Practitioners are required to document this interaction by keeping a signature log of all patients who have received this written information. These records are required to be kept for a period of five years and shall be readily available for inspection.

(4) A prescribing practitioner who chooses to dispense prescription medications shall meet the standards set forth in R156-17b-602 through R156-17b-605 and R156-17b-609 through R156-17b-611.

([~~3~~]5) In accordance with Subsections 58-17b-309(4)(c) and 58-17b-309.5(2)(b)(viii), a prescribing practitioner or

optometrist who chooses to dispense a cosmetic drug, [~~or~~]a prescribing practitioner who chooses to dispense an injectable weight loss drug, as listed in Subsections (1) and (2), or a prescribing practitioner or the prescribing practitioner's employee who chooses to dispense drugs used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient to the prescribing practitioner's or optometrist's patients shall have a label securely affixed to the container indicating the following minimum information:

(a) the name, address and telephone number of the prescribing practitioner or optometrist prescribing and dispensing the drug;

(b) the serial number of the prescription as assigned by the dispensing prescribing practitioner or optometrist;

(c) the filling date of the prescription or its last dispensing date;

(d) the name of the patient;

(e) the directions for use and cautionary statements, if any, which are contained in the prescription order or are needed;

(f) the trade, generic or chemical name, amount dispensed and the strength of dosage form; and

(g) the beyond use date.

([~~4~~]6) A prescribing practitioner or optometrist who chooses to dispense a cosmetic drug, or a prescribing practitioner who chooses to dispense an injectable weight loss drug, as listed in Subsections (1) and (2), or a prescribing practitioner or the prescribing practitioner's employee who chooses to dispense drugs used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient shall keep inventory records for each drug dispensed pursuant to R156-17b-605 and a prescription dispensing medication profile for each patient receiving a drug dispensed by the prescribing practitioner or optometrist pursuant to R156-17b-609. Those records shall be made available to the Division upon request by the Division.

(a) The general requirements for an inventory of drugs dispensed by a prescribing practitioner, the prescribing practitioner's employee, or optometrist include:

(i) the prescribing practitioner or optometrist shall be responsible for taking all required inventories, but may delegate the performance of taking the inventory to another person;

(ii) the inventory records [~~must~~]shall be maintained for a period of five years and be readily available for inspection;

(iii) the inventory records shall be filed separately from all other records;

(iv) the person taking the inventory and the prescribing practitioner or optometrist shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the prescribing practitioner or optometrist and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory;

(v) the initial inventory shall be completed within three working days of the date on which the prescribing practitioner or optometrist begins to dispense a drug under Sections 58-17b-309 and 58-17b-309.5; and

(vi) the annual inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs.

(b) A prescription dispensing medication profile shall be maintained for every patient receiving a drug that is dispensed by a prescribing practitioner or optometrist in accordance with Section 58-17b-309 and 58-17b-309.5 for a period of at least one year from the date of the most recent prescription fill or refill. The medication profile shall be kept as part of the patient's medical record and include, as a minimum, the following information:

(i) full name of the patient, address, telephone number, date of birth or age, and gender;

(ii) patient history where significant, including known allergies and drug reactions; and

(iii) a list of drugs being dispensed including:

(A) name of prescription drug;

(B) strength of prescription drug;

(C) quantity dispensed;

(D) prescription drug lot number and name of manufacturer;

(E) date of filling or refilling;

(F) charge for the prescription drug as dispensed to the patient;

(G) any additional comments relevant to the patient's drug use; and

(H) documentation that patient counseling was provided in accordance with Subsection ([~~5~~]7).

([~~5~~]7) A prescribing practitioner or optometrist who is dispensing a cosmetic drug or injectable weight loss drug listed in Subsections (1) and (2) in accordance with Subsection 58-17b-309(4)(c), or a prescribing practitioner or the prescribing practitioner's employee who chooses to dispense drugs used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient in accordance with Section 58-17b-309.5,

shall include the following elements when providing patient counseling:

(a) the name and description of the prescription drug;

(b) the dosage form, dose, route of administration and duration of drug therapy;

(c) intended use of the drug and expected action;

(d) special directions and precautions for preparation, administration and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescription refill information;

(i) action to be taken in the event of a missed dose;

(j) prescribing practitioner or optometrist comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; and

(k) the date after which the prescription should not be taken or used, or the beyond use date.

([~~6~~]8) In accordance with Subsection 58-17b-309(4)(c), the medication storage standards that [~~must~~]shall be maintained by a prescribing practitioner or optometrist who dispenses a drug under Subsections (1) and (2), or a prescribing practitioner or the prescribing practitioner's employee who chooses to dispense drugs used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient in accordance with Section 58-17b-309.5, provides that the storage space shall be:

(a) kept in an area that is well lighted, well ventilated, clean and sanitary;

(b) equipped to permit the orderly storage of prescription drugs in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the drug inventory;

(c) equipped with a security system to permit detection of entry at all times when the prescribing practitioner's or optometrist's office or clinic is closed;

(d) at a temperature which is maintained within a range compatible with the proper storage of drugs; and

(e) securely locked with only the prescribing practitioner or optometrist having access when the prescribing practitioner's or optometrist's office or clinic is closed.

([~~7~~]9) In accordance with Subsections 58-17b-309(5) and 58-17b-309.5(1)(b), if a cosmetic drug or a weight loss drug listed in Subsections (1) and (2), or a drug used to treat cancer, manage its symptoms, or provide continuity of care for a

cancer patient requires reconstitution or compounding to prepare the drug for administration, the prescribing practitioner or optometrist shall follow the USP-NF 797 standards for sterile compounding.

([~~8~~]10) In accordance with Subsection 58-17b-309(5), factors that shall be considered by licensing boards when determining if a drug may be dispensed by a prescribing practitioner, the prescribing practitioner's employee or optometrist, include whether:

(a)(i) the drug has FDA approval;

(ii)(A) is prescribed and dispensed for the conditions or indication for which the drug was approved to treat; or

(B) the prescribing practitioner or optometrist takes full responsibility for prescribing and dispensing a drug for off-label use;

(b) the drug has been approved for self administration by the FDA;

(c) the stability of the drug is adequate for the supply being dispensed; and

(d) the drug can be safely dispensed by a prescribing practitioner or optometrist.

(11) Standards for reporting to the Utah Controlled Substance Database shall be the same standards as set forth in the Utah Controlled Substance Database Act, Title 58, Chapter 37f, and the Utah Controlled Substance Database Act Rule, R156-37f.

R156-17b-601. Operating Standards - Pharmacy Technician.

In accordance with Subsection 58-17b-102(5[~~5~~]4), practice as a licensed pharmacy technician is defined as follows:

(1) The pharmacy technician may perform any task associated with the physical preparation and processing of prescription and medication orders including:

(a) receiving written prescriptions;

(b) taking refill orders;

(c) entering and retrieving information into and from a database or patient profile;

(d) preparing labels;

(e) retrieving medications from inventory;

(f) counting and pouring into containers;

(g) placing medications into patient storage containers;

(h) affixing labels;

(i) compounding;

(j) counseling for over-the-counter drugs and dietary supplements under the direction of the supervising pharmacist as referenced in Subsection [~~R156-17b-304(3)(ix)~~]58-17b-102(55)(b)(2);

(k) accepting new prescription drug orders left on voicemail for a pharmacist to review; and

(l) additional tasks not requiring the judgment of a pharmacist.

(2) The pharmacy technician shall not receive new verbal prescriptions or medication orders, clarify prescriptions or medication orders nor perform drug utilization reviews.

(3) Pharmacy technicians, including no more than one pharmacy technician-in-training per shift, shall have direct supervision by a pharmacist in accordance with Subsection R156-17b-603([~~19~~]2)(s).

R156-17b-604. Operating Standards - Closing a Pharmacy.

At least 14 days prior to the closing of a pharmacy, the PIC shall comply with the following:

(1) If the pharmacy is registered to possess controlled substances, send a written notification to the appropriate regional office of the Drug Enforcement Administration (DEA) containing the following information:

(a) the name, address and DEA registration number of the pharmacy;

(b) the anticipated date of closing;

(c) the name, address and DEA registration number of the pharmacy acquiring the controlled substances; and

(d) the date on which the transfer of controlled substances will occur.

(2) If the pharmacy dispenses prescription drug orders, post a closing notice sign in a conspicuous place in the front of the prescription department and at all public entrance doors to the pharmacy. Such closing notice shall contain the following information:

(a) the date of closing; and

(b) the name, address and telephone number of the pharmacy acquiring the prescription drug orders, including refill information and patient medication records of the pharmacy.

(3) On the date of closing, the PIC shall remove all prescription drugs from the pharmacy by one or a combination of the following methods:

(a) return prescription drugs to manufacturer or supplier for credit or disposal; or

(b) transfer, sell or give away prescription drugs to a person who is legally entitled to possess drugs, such as a hospital or another pharmacy.

(4) If the pharmacy dispenses prescription drug orders:

(a) transfer the prescription drug order files, including refill information and patient medication records, to a licensed pharmacy within a reasonable distance of the closing pharmacy;

and

(b) move all signs or notify the landlord or owner of the property that it is unlawful to use the word "pharmacy", or any other word or combination of words of the same or similar meaning, or any graphic representation that would mislead or tend to mislead the public that a pharmacy is located at this address.

(5) Within 10 days of the closing of the pharmacy, the PIC shall forward to the Division a written notice of the closing that includes the following information:

(a) the actual date of closing;

(b) the license issued to the pharmacy;

(c) a statement attesting:

(i) that an inventory as specified in Subsection R156-17b-605([~~6~~]5) has been conducted; and

(ii) the manner in which the legend drugs and controlled substances possessed by the pharmacy were transferred or disposed;

(d) if the pharmacy dispenses prescription drug orders, the name and address of the pharmacy to which the prescription drug orders, including refill information and patient medication records, were transferred.

(6) If the pharmacy is registered to possess controlled substances, a letter [~~must~~]shall be sent to the appropriate DEA regional office explaining that the pharmacy has closed. The letter shall include the following items:

(a) DEA registration certificate;

(b) all unused DEA order forms (Form 222) with the word "VOID" written on the face of each order form; and

(c) copy #2 of any DEA order forms (Form 222) used to transfer Schedule II controlled substances from the closed pharmacy.

(7) If the pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy or other emergency circumstances and the PIC cannot provide notification 14 days prior to the closing, the PIC shall comply with the provisions of Subsection (1) as far in advance of the closing as allowed by the circumstances.

(8) If the PIC is not available to comply with the requirements of this section, the owner or legal representative shall be responsible for compliance with the provisions of this section.

R156-17b-605. Operating Standards - Inventory Requirements.

(1) General requirements for inventory of a pharmacy shall include the following:

(a) the PIC shall be responsible for taking all required

inventories, but may delegate the performance of the inventory to another person or persons;

(b) the inventory records [~~must~~]shall be maintained for a period of five years and be readily available for inspection;

(c) the inventory records shall be filed separately from all other records;

(d) the inventory records shall be in a typewritten or printed form and include all stocks of controlled substances on hand on the date of the inventory including any that are out of date drugs and drugs in automated pharmacy systems. An inventory taken by use of a verbal recording device [~~must~~]shall be promptly transcribed;

(e) the inventory may be taken either as of the opening of the business or the close of business on the inventory date;

(f) the person taking the inventory and the PIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory;

(g) the person taking the inventory shall make an exact count or measure all controlled substances listed in Schedule I or II;

(h) the person taking the inventory shall make an estimated count or measure all Schedule III, IV or V controlled substances, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents [~~must~~]shall be made;

(i) the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances;[~~and~~]

(j) if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventoried, the perpetual inventory shall be reconciled on the date of the inventory; and

(k) all out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the date of expiration imprinted on the label.

(2) Requirement for taking the initial inventory shall include the following:

(a) all pharmacies having any stock of controlled substances shall take an inventory on the opening day of business. Such inventory shall include all controlled substances including any out-of-date drugs and drugs in automated pharmacy systems;

(b) in the event a pharmacy commences business with none of the drugs specified in paragraph (2)(a) of this section on

hand, the pharmacy shall record this fact as the initial inventory;[~~ and~~]

(c) the initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection (3) of this section; and

(d) when combining two pharmacies, each pharmacy shall:

(i) conduct a separate closing pharmacy inventory of controlled substances on the date of closure; and

(ii) conduct a combined opening inventory of controlled substances for the new pharmacy prior to opening.

(3) Requirement for annual inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems.

(4) Requirements for change of ownership shall include the following:

(a) a pharmacy that changes ownership shall take an inventory of all legend drugs and controlled substances including out-of-date drugs and drugs in automated pharmacy systems on the date of the change of ownership;

(b) such inventory shall constitute, for the purpose of this section, the closing inventory for the seller and the initial inventory for the buyer; and

(c) transfer of Schedule I and II controlled substances shall require the use of official DEA order forms (Form 222).

(5) Requirement for taking inventory when closing a pharmacy includes the PIC, owner, or the legal representative of a pharmacy that ceases to operate as a pharmacy shall forward to the Division, within ten days of cessation of operation, a statement attesting that an inventory has been conducted, the date of closing and a statement attesting the manner by which legend drugs and controlled substances possessed by the pharmacy were transferred or disposed.[

~~(6) Requirements specific to taking inventory in a Class B pharmacy shall include the following:~~

~~(a) all Class B pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances which shall be reconciled according to facility policy; and~~

~~(b) the inventory of the institution shall be maintained in the pharmacy; if an inventory is conducted in other departments within the institution, the inventory shall be listed separately as follows:~~

~~(i) the inventory of drugs on hand in the pharmacy shall be listed separately from the inventory of drugs on hand in the other areas of the institution; and~~

~~(ii) the inventory of the drugs on hand in all other~~

~~departments shall be identified by department.~~

~~(7) All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the date of expiration imprinted on the label.~~]

R156-17b-610. Operating Standards - Patient Counseling.

In accordance with Subsection 58-17b-601(1), guidelines for providing patient counseling established in Section 58-17b-613 include the following:

(1) Based upon the pharmacist's or pharmacy intern's professional judgment, patient counseling may be discussed to include the following elements:

(a) the name and description of the prescription drug;

(b) the dosage form, dose, route of administration and duration of drug therapy;

(c) intended use of the drug, when known, and expected action;

(d) special directions and precautions for preparation, administration and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescription refill information;

(i) action to be taken in the event of a missed dose;

(j) pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; and

(k) the date after which the prescription should not be taken or used, or the beyond use date.

(2) Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drugs.

(3) A pharmacist shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation.

(4) The offer to counsel shall be documented and said documentation shall be available to the Division. These records [~~must~~]shall be maintained for a period of five years and be available for inspection within 7-10 business days.

(5) Counseling shall be:

(a) provided with each new prescription drug order, once yearly on maintenance medications, and if the pharmacist deems appropriate with prescription drug refills;

(b) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent; and

(c) communicated verbally in person unless the patient or the patient's agent is not at the pharmacy or a specific communication barrier prohibits such verbal communication.

(6) Only a pharmacist or pharmacy intern may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs.

(7) In addition to the requirements of Subsections (1) through (6) of this section, if a prescription drug order is delivered to the patient at the pharmacy, a filled prescription may not be delivered to a patient unless a pharmacist is in the pharmacy. However, an agent of the pharmacist may deliver a prescription drug order to the patient or the patient's agent if the pharmacist is absent for ten minutes or less and provided a record of the delivery is maintained and contains the following information:

(a) date of the delivery;

(b) unique identification number of the prescription drug order;

(c) patient's name;

(d) patient's phone number or the phone number of the person picking up the prescription; and

(e) signature of the person picking up the prescription.

(8) If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable:

(a) the information specified in Subsection (1) of this section shall be delivered with the dispensed prescription in writing;

(b) if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."; and

(c) written information provided in Subsection (8)(b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.

R156-17b-612. Operating Standards - Prescriptions.

In accordance with Subsection 58-17b-601(1), the following shall apply to prescriptions:

(1) Prescription orders for controlled substances (including prescription transfers) shall be handled according to the rules of the Federal Drug Enforcement Administration.

(2) A prescription issued by an authorized licensed practitioner, if verbally communicated by an agent of that practitioner upon that practitioner's specific instruction and authorization, may be accepted by a pharmacist or pharmacy intern.

(3) A prescription issued by a licensed prescribing practitioner, if electronically communicated by an agent of that practitioner, upon that practitioner's specific instruction and authorization, may be accepted by a pharmacist, pharmacy intern and pharmacy technician.

(4) In accordance with Sections 58-17b-609 and 58-17b-611, prescription files, including refill information, shall be maintained for a minimum of five years and shall be immediately retrievable in written or electronic format.

(5) Prescriptions for legend drugs having a remaining authorization for refill may be transferred by the pharmacist or pharmacy intern at the pharmacy holding the prescription to a pharmacist or pharmacy intern at another pharmacy upon the authorization of the patient to whom the prescription was issued or electronically as authorized under Subsection R156-17b-613(9). The transferring pharmacist or pharmacy intern and receiving pharmacist or pharmacy intern shall act diligently to ensure that the total number of authorized refills is not exceeded. The following additional terms apply to such a transfer:

(a) the transfer shall be communicated directly between pharmacists or pharmacy interns or as authorized under Subsection R156-17b-613(9);

(b) both the original and the transferred prescription drug orders shall be maintained for a period of five years from the date of the last refill;

(c) the pharmacist or pharmacy intern transferring the prescription drug order shall void the prescription electronically or write void/transfer on the face of the invalidated prescription manually;

(d) the pharmacist or pharmacy intern receiving the transferred prescription drug order shall:

(i) indicate on the prescription record that the prescription was transferred electronically or manually; and

(ii) record on the transferred prescription drug order the following information:

(A) original date of issuance and date of dispensing or

receipt, if different from date of issuance;

(B) original prescription number and the number of refills authorized on the original prescription drug order;

(C) number of valid refills remaining and the date of last refill, if applicable;

(D) the name and address of the pharmacy and the name of the pharmacist or pharmacy intern to which such prescription is transferred; and

(E) the name of the pharmacist or pharmacy intern transferring the prescription drug order information;

(e) the data processing system shall have a mechanism to prohibit the transfer or refilling of legend drugs or controlled substance prescription drug orders which have been previously transferred; and

(f) a pharmacist or pharmacy intern may not refuse to transfer original prescription information to another pharmacist or pharmacy intern who is acting on behalf of a patient and who is making a request for this information as specified in Subsection (12) of this section.

(6) Prescriptions for terminal patients in licensed hospices, home health agencies or nursing homes may be partially filled if the patient has a medical diagnosis documenting a terminal illness and may not need the full prescription amount.

(7) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order;

(8) If there are no refill instructions on the original prescription drug order, or if all refills authorized on the original prescription drug order have been dispensed, authorization from the prescribing practitioner [~~must~~]shall be obtained prior to dispensing any refills.

(9) Refills of prescription drug orders for legend drugs may not be refilled after one year from the date of issuance of the original prescription drug order without obtaining authorization from the prescribing practitioner prior to dispensing any additional quantities of the drug.

(10) Refills of prescription drug orders for controlled substances shall be done in accordance with Subsection 58-37-6(7)(f).

(11) A pharmacist may exercise his professional judgment in refilling a prescription drug order for a drug, other than a controlled substance listed in Schedule II, without the authorization of the prescribing practitioner, provided:

(a) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(b) either:

(i) a natural or manmade disaster has occurred which prohibits the pharmacist from being able to contact the practitioner; or

(ii) the pharmacist is unable to contact the practitioner after a reasonable effort, the effort should be documented and said documentation should be available to the Division;

(c) the quantity of prescription drug dispensed does not exceed a 72-hour supply, unless the packaging is in a greater quantity;

(d) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the practitioner is required for future refills;

(e) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

(f) the pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection; and

(g) the pharmacist affixes a label to the dispensing container as specified in Section 58-17b-602.

(12) If the prescription was originally filled at another pharmacy, the pharmacist may exercise his professional judgment in refilling the prescription provided:

(a) the patient has the prescription container label, receipt or other documentation from the other pharmacy which contains the essential information;

(b) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;

(c) the pharmacist, in his professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of (a) and (b) of this subsection; and

(d) the pharmacist complies with the requirements of Subsections (11)(c) through (g) of this section.

(13) The address specified in Subsection 58-17b-602(1)(b) shall be a physical address, not a post office box.

(14) In accordance with Subsection 58-37-6(7)(e), a prescription may not be written, issued, filled, or dispensed for a Schedule I controlled substance unless:

(a) the person who writes the prescription is licensed to prescribe Schedule I controlled substances; and

(b) the prescribed controlled substance is to be used in research.

R156-17b-613. Operating Standards - Issuing Prescription Orders by Electronic Means.

In accordance with Subsections 58-17b-102(28) [~~and~~]through (29), [~~and~~]58-17b-602(1), R156-82, and R156-1, prescription orders may be issued by electronic means of communication according to the following standards:

(1) Prescription orders for Schedule II - V controlled substances received by electronic means of communication shall be handled according to Part 1304.04 of Section 21 of the CFR.

(2) Prescription orders for non-controlled substances received by electronic means of communication may be dispensed by a pharmacist or pharmacy intern only if all of the following conditions are satisfied:

(a) all electronically transmitted prescription orders shall include the following:

(i) all information that is required to be contained in a prescription order pursuant to Section 58-17b-602;

(ii) the time and date of the transmission, and if a facsimile transmission, the electronically encoded date, time and fax number of the sender; and

(iii) the name of the pharmacy intended to receive the transmission;

(b) the prescription order shall be transmitted under the direct supervision of the prescribing practitioner or his designated agent;

(c) the pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the transmitted prescription. Practitioners or their agents transmitting medication orders using electronic equipment are to provide voice verification when requested by the pharmacist receiving the medication order. The pharmacist is responsible for assuring that each electronically transferred prescription order is valid and shall authenticate a prescription order issued by a prescribing practitioner which has been transmitted to the dispensing pharmacy before filling it, whenever there is a question;

(d) a practitioner may authorize an agent to electronically transmit a prescription provided that the identifying information of the transmitting agent is included on the transmission. The practitioner's electronic signature, or other secure method of validation, shall be provided with the electronic prescription; and

(e) an electronically transmitted prescription order that meets the requirements above shall be deemed to be the original prescription.

(3) This section does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical facilities.

(4) No agreement between a prescribing practitioner and a

pharmacy shall require that prescription orders be transmitted by electronic means from the prescribing practitioner to that pharmacy only.

(5) The pharmacist shall retain a printed copy of an electronic prescription, or a record of an electronic prescription that is readily retrievable and printable, for a minimum of five years. The printed copy shall be of non-fading legibility.

(6) Wholesalers, distributors, manufacturers, pharmacists and pharmacies shall not supply electronic equipment to any prescriber for transmitting prescription orders.

(7) An electronically transmitted prescription order shall be transmitted to the pharmacy of the patient's choice.

(8) Prescription orders electronically transmitted to the pharmacy by the patient shall not be filled or dispensed.

(9) A prescription order for a legend drug or controlled substance in Schedule III through V may be transferred up to the maximum refills permitted by law or by the prescriber by electronic transmission providing the pharmacies share a real-time, on-line database provided that:

(a) the information required to be on the transferred prescription has the same information as described in Subsection R156-17b-612(5)(a) through (f); and

(b) pharmacists, pharmacy interns or pharmacy technicians electronically accessing the same prescription drug order records may electronically transfer prescription information if the data processing system has a mechanism to send a message to the transferring pharmacy containing the following information:

(i) the fact that the prescription drug order was transferred;

(ii) the unique identification number of the prescription drug order transferred;

(iii) the name of the pharmacy to which it was transferred; and

(iv) the date and time of the transfer.

R156-17b-614a. Operating Standards - Operating Standards, Class A and B Pharmacy.

(1) In accordance with Subsection 58-17b-601(1), standards for the operations for a Class A and Class B pharmacy include:

(a) shall be well lighted, well ventilated, clean and sanitary;

(b) the dispensing area, if any, shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. This does not apply to clean rooms where sterile products are prepared. Clean rooms should not have sinks or floor drains that expose the area to an open sewer. All

required equipment shall be clean and in good operating condition;

(c) be equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory;

(d) be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility;

(e) be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare; and

(f) be equipped with a security system to permit detection of entry at all times when the facility is closed.

(2) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator and freezer shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing.

(3) Facilities engaged in [~~extensive~~]compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:

(a) [~~must~~]shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations;

(b) may compound in anticipation of receiving prescriptions in limited amounts;

(c) bulk active ingredients [~~must~~]shall:

(i) be procured from a facility registered with the federal Food and Drug Administration; and [~~be component of FDA approved drugs listed in the approved drug products prepared by the Center for Drug Evaluation and Research of the FDA;~~]

(ii) not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness;

(d) [~~compounding using drugs that are not part of a FDA approved drug listed in the approved drug products prepared by the Center for Drug Evaluation and Research of the FDA requires an investigational new drug application (IND). The IND approval shall be kept in the pharmacy for five years for inspection;~~

~~(e)~~]a master worksheet sheet shall be developed and approved by a pharmacist for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a

duplicate of the master worksheet sheet shall be used as the preparation worksheet sheet from which each batch is prepared and on which all documentation for that batch occurs. The master worksheet sheet shall contain at a minimum:

(i) the formula;

(ii) the components;

(iii) the compounding directions;

(iv) a sample label;

(v) evaluation and testing requirements;

(vi) sterilization methods, if applicable;

(vii) specific equipment used during preparation such as specific compounding device; and

(viii) storage requirements;

([~~f~~]e) a preparation worksheet sheet for each batch of sterile or non-sterile pharmaceuticals shall document the following:

(i) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;

(ii) manufacturer lot number for each component;

(iii) component manufacturer or suitable identifying number;

(iv) container specifications (e.g. syringe, pump cassette);

(v) unique lot or control number assigned to batch;

(vi) expiration date of batch prepared products;

(vii) date of preparation;

(viii) name, initials or electronic signature of the person or persons involved in the preparation;

(ix) names, initials or electronic signature of the responsible pharmacist;

(x) end-product evaluation and testing specifications, if applicable; and

(xi) comparison of actual yield to anticipated yield, when appropriate;

([~~g~~]f) the label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum:

(i) the unique lot number assigned to the batch;

(ii) all solution and ingredient names, amounts, strengths and concentrations, when applicable;

(iii) quantity;

(iv) expiration date and time, when applicable;

(v) appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and

(vi) device-specific instructions, where appropriate;

([~~h~~]g) the expiration date assigned shall be based on currently available drug stability information and sterility

considerations or appropriate in-house or contract service stability testing;

(i) sources of drug stability information shall include the following:

(A) references can be found in Trissel's "Handbook on Injectable Drugs", [~~16~~]17th Edition, October [~~27, 2010~~]31, 2012;

(B) manufacturer recommendations; and

(C) reliable, published research;

(ii) when interpreting published drug stability information, the pharmacist shall consider all aspects of the final sterile product being prepared such as drug reservoir, drug concentration and storage conditions; and

(iii) methods for establishing expiration dates shall be documented; and

([~~i~~]h) there shall be a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follows the USP-NF Chapters 795 and 797 standards.

(4) The facility shall have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel:

(a) Title 58, Chapter 1, Division of Occupational and Professional Licensing Act'

(b) R156-1, General Rule[~~s~~] of the Division of Occupational and Professional Licensing;

(c) Title 58, Chapter 17b, Pharmacy Practice Act;

(d) R156-17b, Utah Pharmacy Practice Act Rule;

(e) Title 58, Chapter 37, Utah Controlled Substances Act;

(f) R156-37, Utah Controlled Substances Act Rule;

(g) Title 58, Chapter 37f, Controlled Substance Database Act;

(h) R156-37f, Controlled Substance Database Act Rule;

(i) Code of Federal Regulations (CFR) 21, Food and Drugs, Part 1300 to end or equivalent such as the USP DI Drug Reference Guides;

(j) current FDA Approved Drug Products (orange book); and

(k) any other general drug references necessary to permit practice dictated by the usual and ordinary scope of practice to be conducted within that facility.

(5) The facility shall post the license of the facility and the license or a copy of the license of each pharmacist, pharmacy intern and pharmacy technician who is employed in the facility, but may not post the license of any pharmacist, pharmacy intern or pharmacy technician not actually employed in the facility.

(6) Facilities shall have a counseling area to allow for

confidential patient counseling, where applicable.

(7) If the pharmacy is located within a larger facility such as a grocery or department store, and a licensed Utah pharmacist is not immediately available in the facility, the pharmacy shall not remain open to pharmacy patients and shall be locked in such a way as to bar entry to the public or any non-pharmacy personnel. All pharmacies located within a larger facility shall be locked and enclosed in such a way as to bar entry by the public or any non-pharmacy personnel when the pharmacy is closed.

(8) Only a licensed Utah pharmacist or authorized pharmacy personnel shall have access to the pharmacy when the pharmacy is closed.

(9) The facility shall maintain a permanent log of the initials or identification codes which identify each dispensing pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified; therefore identical initials or identification codes shall not be used.

(10) The pharmacy facility [~~must~~]shall maintain copy 3 of DEA order form (Form 222) which has been properly dated, initialed and filed and all copies of each unaccepted or defective order form and any attached statements or other documents.

(11) If applicable, a hard copy of the power of attorney authorizing a pharmacist to sign DEA order forms (Form 222) [~~must~~]shall be available to the Division whenever necessary.

(12) Pharmacists or other responsible individuals shall verify that the suppliers' invoices of legend drugs, including controlled substances, are listed on the invoices and were actually received by clearly recording their initials and the actual date of receipt of the controlled substances.

(13) The pharmacy facility [~~must~~]shall maintain a record of suppliers' credit memos for controlled substances and legend drugs.

(14) A copy of inventories required under Section R156-17b-605 [~~must~~]shall be made available to the Division when requested.

(15) The pharmacy facility [~~must~~]shall maintain hard copy reports of surrender or destruction of controlled substances and legend drugs submitted to appropriate state or federal agencies.

(16) If the pharmacy includes a drop/false ceiling, the pharmacy's perimeter walls [~~must~~]shall extend to the hard deck, or other measures [~~must~~]shall be taken to prevent unauthorized entry into the pharmacy.

R156-17b-614b. Operating Standards - Class B pharmacy

designated as a Branch Pharmacy.

In accordance with Subsections 58-17b-102([~~7~~]8) and 58-1-301(3), the qualifications for designation as a branch pharmacy include the following:

(1) The Division, in collaboration with the Board, shall approve the location of each branch pharmacy. The following shall be considered in granting such designation:

(a) the distance between or from nearby alternative pharmacies and all other factors affecting access of persons in the area to alternative pharmacy resources;

(b) the availability at the location of qualified persons to staff the pharmacy, including the physician, physician assistant or advanced practice registered nurse;

(c) the availability and willingness of a parent pharmacy and supervising pharmacist to assume responsibility for the branch pharmacy;

(d) the availability of satisfactory physical facilities in which the branch pharmacy may operate; and

(e) the totality of conditions and circumstances which surround the request for designation.

(2) A branch pharmacy shall be licensed as a pharmacy branch of an existing Class A or B pharmacy licensed by the Division.

(3) The application for designation of a branch pharmacy shall be submitted by the licensed parent pharmacy seeking such designation. In the event that more than one licensed pharmacy makes application for designation of a branch pharmacy location at a previously undesignated location, the Division in collaboration with the Board shall review all applications for designation of the branch pharmacy and, if the location is approved, shall approve for licensure the applicant determined best able to serve the public interest as identified in Subsection (1).

(4) The application shall include the following:

(a) complete identifying information concerning the applying parent pharmacy;

(b) complete identifying information concerning the designated supervising pharmacist employed at the parent pharmacy;

(c) address and description of the facility in which the branch pharmacy is to be located;

(d) specific formulary to be stocked indicating with respect to each prescription drug, the name, the dosage strength and dosage units in which the drug will be prepackaged;

(e) complete identifying information concerning each person located at the branch pharmacy who will dispense prescription drugs in accordance with the approved protocol; and

(f) protocols under which the branch pharmacy will operate and its relationship with the parent pharmacy to include the following:

(i) the conditions under which prescription drugs will be stored, used and accounted for;

(ii) the method by which the drugs will be transported from parent pharmacy to the branch pharmacy and accounted for by the branch pharmacy; and

(iii) a description of how records will be kept with respect to:

(A) formulary;

(B) changes in formulary;

(C) record of drugs sent by the parent pharmacy;

(D) record of drugs received by the branch pharmacy;

(E) record of drugs dispensed;

(F) periodic inventories; and

(G) any other record contributing to an effective audit trail with respect to prescription drugs provided to the branch pharmacy.

R156-17b-614e. Class B - [~~Hospital Pharmacy and Emergency Department Treatment~~]Dispensing Drugs from an Emergency Department and Upon Discharge from a Rural Hospital Pharmacy.

The "Guidelines for Hospital Pharmacies and Emergency Department Treatment" document, adopted May 21, 2012, by the Division in collaboration with the Utah State Board of Pharmacy, as posted on the Division website, is the guideline or standard to be utilized by rural hospital emergency departments dispensing a short course of necessary medications to patients when a pharmacy is not open to fill their prescriptions.

R156-17b-615. Operating Standards - Class C Pharmacy - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer in Utah.

In accordance with Subsections 58-17b-102(4[~~8~~]6) and 58-17b-601(1), the operating standards for Class C pharmacies designated as pharmaceutical wholesaler/distributor and pharmaceutical manufacturer licensees includes the following:

(1) Every pharmaceutical wholesaler or manufacturer that engages in the wholesale distribution and manufacturing of drugs or medical devices located in this state shall be licensed by the Division. A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs. Business names cannot be identical to the name used by another unrelated wholesaler licensed to purchase drugs and devices in Utah.

(2) Manufacturers distributing only their own FDA-approved

prescription drugs or co-licensed product shall satisfy this requirement by registering their establishment with the Federal Food and Drug Administration pursuant to 21 CFR Part 207 and submitting the information required by 21 CFR Part 205, including any amendments thereto, to the Division.

(3) An applicant for licensure as a pharmaceutical wholesale distributor [~~must~~]shall provide the following minimum information:

(a) All trade or business names used by the licensee (including "doing business as" and "formerly known as");

(b) Name of the owner and operator of the license as follows:

(i) if a person, the name, business address, social security number and date of birth;

(ii) if a partnership, the name, business address, and social security number and date of birth of each partner, and the partnership's federal employer identification number;

(iii) if a corporation, the name, business address, social security number and date of birth, and title of each corporate officer and director, the corporate names, the name of the state of incorporation, federal employer identification number, and the name of the parent company, if any, but if a public[~~al~~]ly traded corporation, the social security number and date of birth for each corporate officer shall not be required;

(iv) if a sole proprietorship, the full name, business address, social security number and date of birth of the sole proprietor and the name and federal employer identification number of the business entity;

(v) if a limited liability company, the name of each member, social security number of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and

(c) any other relevant information required by the Division.

(4) The licensed facility need not be under the supervision of a licensed pharmacist, but shall be under the supervision of a designated representative who meets the following criteria:

(a) is at least 21 years of age;

(b) has been employed full time for at least three years in a pharmacy or with a pharmaceutical wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to prescription drugs;

(c) is employed by the applicant full time in a managerial level position;

(d) is actively involved in and aware of the actual daily

operation of the pharmaceutical wholesale distribution;

(e) is physically present at the facility during regular business hours, except when the absence of the designated representative is authorized, including but not limited to, sick leave and vacation leave; and

(f) is serving in the capacity of a designated representative for only one licensee at a time.

(5) The licensee shall provide the name, business address, and telephone number of a person to serve as the designated representative for each facility of the pharmaceutical wholesaler that engages in the distribution of drugs or devices.

(6) Each facility that engages in pharmaceutical wholesale distribution and manufacturing facilities [~~must~~]shall undergo an inspection by the Division for the purposes of inspecting the pharmaceutical wholesale distribution or manufacturing operation prior to initial licensure and periodically thereafter with a schedule to be determined by the Division.

(7) All pharmaceutical wholesalers and manufacturer [~~must~~]shall publicly display or have readily available all licenses and the most recent inspection report administered by the Division.

(8) All Class C pharmacies shall:

(a) be of suitable size and construction to facilitate cleaning, maintenance and proper operations;

(b) have storage areas designed to provide adequate lighting, ventilation, sanitation, space, equipment and security conditions;

(c) have the ability to control temperature and humidity within tolerances required by all prescription drugs and prescription drug precursors handled or used in the distribution or manufacturing activities of the applicant or licensee;

(d) provide for a quarantine area for storage of prescription drugs and prescription drug precursors that are outdated, damaged, deteriorated, misbranded, adulterated, opened or unsealed containers that have once been appropriately sealed or closed or in any other way unsuitable for use or entry into distribution or manufacturing;

(e) be maintained in a clean and orderly condition; and

(f) be free from infestation by insects, rodents, birds or vermin of any kind.

(9) Each facility used for wholesale drug distribution or manufacturing of prescription drugs shall:

(a) be secure from unauthorized entry;

(b) limit access from the outside to a minimum in conformance with local building codes, life and safety codes and control access to persons to ensure unauthorized entry is not made;

(c) limit entry into areas where prescription drugs, prescription drug precursors, or prescription drug devices are held to authorized persons who have a need to be in those areas;

(d) be well lighted on the outside perimeter;

(e) be equipped with an alarm system to permit detection of entry and notification of appropriate authorities at all times when the facility is not occupied for the purpose of engaging in distribution or manufacturing of prescription drugs; and

(f) be equipped with security measures, systems and procedures necessary to provide reasonable security against theft and diversion of prescription drugs or alteration or tampering with computers and records pertaining to prescription drugs or prescription drug precursors.

(10) Each facility shall provide the storage of prescription drugs, prescription drug precursors, and prescription drug devices in accordance with the following:

(a) all prescription drugs and prescription drug precursors shall be stored at appropriate temperature, humidity and other conditions in accordance with labeling of such prescription drugs or prescription drug precursors or with requirements in the USP-NF;

(b) if no storage requirements are established for a specific prescription drug, prescription drug precursor, or prescription drug devices, the products shall be held in a condition of controlled temperature and humidity as defined in the USP-NF to ensure that its identity, strength, quality and purity are not adversely affected; and

(c) there shall be established a system of manual, electromechanical or electronic recording of temperature and humidity in the areas in which prescription drugs, prescription drug precursors, and prescription drug devices are held to permit review of the record and ensure that the products have not been subjected to conditions which are outside of established limits.

(11) Each person who is engaged in pharmaceutical wholesale distribution of prescription drugs for human use that leave, or have ever left, the normal distribution channel shall, before each pharmaceutical wholesale distribution of such drug, provide a pedigree to the person who receives such drug. A retail pharmacy or pharmacy warehouse shall comply with the requirements of this section only if the pharmacy engages in pharmaceutical wholesale distribution of prescription drugs. The pedigree shall:

(a) include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, through acquisition and sale by any

pharmaceutical wholesaler, until sale to a pharmacy or other person dispensing or administering the prescription drug. At a minimum, the necessary chain of distribution information shall include:

(i) name, address, telephone number, and if available, the email address of each owner of the prescription drug, and each pharmaceutical wholesaler of the prescription drug;

(ii) name and address of each location from which the product was shipped, if different from the owner's;

(iii) transaction dates;

(iv) name of the prescription drug;

(v) dosage form and strength of the prescription drug;

(vi) size of the container;

(vii) number of containers;

(viii) lot number of the prescription drug;

(ix) name of the manufacturer of the finished dose form; and

(x) National Drug Code (NDC) number.

(b) be maintained by the purchaser and the pharmaceutical wholesaler for five years from the date of sale or transfer and be available for inspection or use upon a request of an authorized officer of the law.

(12) Each facility shall comply with the following requirements:

(a) in general, each person who is engaged in pharmaceutical wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs that leave the normal distribution channel;

(b) upon receipt, each outside shipping container containing prescription drugs, prescription drug precursors, or prescription drug devices shall be visibly examined for identity and to prevent the acceptance of prescription drugs, prescription drug precursors, or prescription drug devices that are contaminated, reveal damage to the containers or are otherwise unfit for distribution:

(i) prescription drugs, prescription drug precursors, or prescription drug devices that are outdated, damaged, deteriorated, misbranded, adulterated or in any other way unfit for distribution or use in manufacturing shall be quarantined and physically separated from other prescription drugs, prescription drug precursors or prescription drug devices until they are appropriately destroyed or returned to their supplier; and

(ii) any prescription drug or prescription drug precursor

whose immediate sealed or outer secondary sealed container has been opened or in any other way breached shall be identified as such and shall be quarantined and physically separated from other prescription drugs and prescription drug precursors until they are appropriately destroyed or returned to their supplier;

(c) each outgoing shipment shall be carefully inspected for identity of the prescription drug products or devices and to ensure that there is no delivery of prescription drugs or devices that have been damaged in storage or held under improper conditions:

(i) if the conditions or circumstances surrounding the return of any prescription drug or prescription drug precursor cast any doubt on the product's safety, identity, strength, quality or purity, then the drug shall be appropriately destroyed or returned to the supplier, unless examination, testing or other investigation proves that the product meets appropriate and applicable standards related to the product's safety, identity, strength, quality and purity;

(ii) returns of expired, damaged, recalled, or otherwise non-saleable prescription drugs shall be distributed by the receiving pharmaceutical wholesale distributor only to the original manufacturer or a third party returns processor that is licensed as a pharmaceutical wholesale distributor under this chapter;

(iii) returns or exchanges of prescription drugs (saleable or otherwise), including any redistribution by a receiving pharmaceutical wholesaler, shall not be subject to the pedigree requirements, so long as they are exempt from the pedigree requirement under the FDA's Prescription Drug Marketing Act guidance or regulations; and

(d) licensee under this Act and pharmacies or other persons authorized by law to dispense or administer prescription drugs for use by a patient shall be accountable for administering their returns process and ensuring that all aspects of their operation are secure and do not permit the entry of adulterated and counterfeit prescription drugs.

(13) A manufacturer or pharmaceutical wholesaler shall furnish prescription drugs only to a person licensed by the Division or to another appropriate state licensing authority to possess, dispense or administer such drugs for use by a patient.

(14) Prescription drugs furnished by a manufacturer or pharmaceutical wholesaler shall be delivered only to the business address of a person described in Subsections R156-17b-102(14)(c) and R156-17b-615(1[4]3), or to the premises listed on the license, or to an authorized person or agent of the licensee at the premises of the manufacturer or pharmaceutical wholesaler if the identity and authority of the authorized agent is

properly established.

(15) Each facility shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription drug precursors and shall make inventories of prescription drugs and prescription drug precursors and required records available for inspection by authorized representatives of the federal, state and local law enforcement agencies in accordance with the following:

(a) there shall be a record of the source of the prescription drugs or prescription drug precursors to include the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

(b) there shall be a record of the identity and quantity of the prescription drug or prescription drug precursor received, manufactured, distributed or shipped or otherwise disposed of by specific product and strength;

(c) there shall be a record of the dates of receipt and distribution or other disposal of any product;

(d) there shall be a record of the identity of persons to whom distribution is made to include name and principal address of the receiver and the address of the location to which the products were shipped;

(e) inventories of prescription drugs and prescription drug precursors shall be made available during regular business hours to authorized representatives of federal, state and local law enforcement authorities;

(f) required records shall be made available for inspection during regular business hours to authorized representatives of federal, state and local law enforcement authorities and such records shall be maintained for a period of two years following disposition of the products; and

(g) records that are maintained on site or immediately retrievable from computer or other electronic means shall be made readily available for authorized inspection during the retention period; or if records are stored at another location, they shall be made available within two working days after request by an authorized law enforcement authority during the two year period of retention.

(16) Each facility shall establish, maintain and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, manufacturing, distribution or other disposal of prescription drugs or prescription drug precursors, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, the policies shall include the following:

(a) a procedure whereby the oldest approved stock of a prescription drug or precursor product is distributed or used first with a provision for deviation from the requirement if such deviation is temporary and appropriate;

(b) a procedure to be followed for handling recalls and withdrawals of prescription drugs adequate to deal with recalls and withdrawals due to:

(i) any action initiated at the request of the FDA or other federal, state or local law enforcement or other authorized administrative or regulatory agency;

(ii) any voluntary action to remove defective or potentially defective drugs from the market; or

(iii) any action undertaken to promote public health, safety or welfare by replacement of existing product with an improved product or new package design;

(c) a procedure to prepare for, protect against or handle any crisis that affects security or operation of any facility in the event of strike, fire, flood or other natural disaster or other situations of local, state or national emergency;

(d) a procedure to ensure that any outdated prescription drugs or prescription drug precursors shall be segregated from other drugs or precursors and either returned to the manufacturer, other appropriate party or appropriately destroyed;

(e) a procedure for providing for documentation of the disposition of outdated, adulterated or otherwise unsafe prescription drugs or prescription drug precursors and the maintenance of that documentation available for inspection by authorized federal, state or local authorities for a period of five years after disposition of the product;

(f) a procedure for identifying, investigating and reporting significant drug inventory discrepancies (involving counterfeit drugs suspected of being counterfeit, contraband, or suspect of being contraband) and reporting of such discrepancies within three (3) business days to the Division and/or appropriate federal or state agency upon discovery of such discrepancies; and

(g) a procedure for reporting criminal or suspected criminal activities involving the inventory of drugs and devices to the Division, FDA and if applicable, Drug Enforcement Administration (DEA), within three (3) business days.

(17) Each facility shall establish, maintain and make available for inspection by authorized federal, state and local law enforcement authorities, lists of all officers, directors, managers and other persons in charge which lists shall include a description of their duties and a summary of their background and qualifications.

(18) Each facility shall comply with laws including:

(a) operating within applicable federal, state and local laws and regulations;

(b) permitting the state licensing authority and authorized federal, state and local law enforcement officials, upon presentation of proper credentials, to enter and inspect their premises and delivery vehicles and to audit their records and written operating policies and procedures, at reasonable times and in a reasonable manner, to the extent authorized by law; and

(c) obtaining a controlled substance license from the Division and registering with the Drug Enforcement Administration (DEA) if they engage in distribution or manufacturing of controlled substances and shall comply with all federal, state and local regulations applicable to the distribution or manufacturing of controlled substances.

(19) Each facility shall be subject to and shall abide by applicable federal, state and local laws that relate to the salvaging or reprocessing of prescription drug products.

(20) A person who is engaged in the wholesale distribution or manufacturing of prescription drugs but does not have a facility located within Utah in which prescription drugs are located, stored, distributed or manufactured is exempt from Utah licensure as a Class C pharmacy, if said person is currently licensed and in good standing in each state of the United States in which that person has a facility engaged in distribution or manufacturing of prescription drugs entered into interstate commerce.

(21) No facility located at the same address shall be dually licensed as both a Class C pharmacy and any other classification of Class A or B pharmacy. Nothing within this section prevents a facility from obtaining licensure for a secondary address which operates separate and apart from any other facility upon obtaining proper licensure.

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